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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/480,472	06/06/1995	SHERROL H. MCDONOUGH	213/066	9286

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/28/2002

64

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/480,472

Applicant(s)

McDonough et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-42, 48-51, 54-56, 67-73, 75, 78-80, 82-84, 86, 88-90, 92, 93, and 95-177 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41, 42, 48, 49, 55, 56, 95, 100, and 102-142 is/are allowed.
- 6) ☒ Claim(s) 39, 40, 50, 51, 54, 67-73, 75, 78-80, 82-84, 86, 88, 96-99, 101, and 143-177 is/are rejected.
- 7) ☒ Claim(s) 89, 90, 92, and 93 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 43
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Attachment for PTO-948

The response, filed 4/2/02, fully has responded to and overcome the previous rejections of record, which were summarized in the Office action, mailed 7/3/01.

Newly applied rejections are herein summarized. Due to these newly applied rejections, the finality of the Office action, mailed 7/3/01, is hereby withdrawn. The amendment, filed 4/2/02, has been entered. Also, this reopening of prosecution is deemed to make the Notice of Appeal, filed 1/3/02, now moot.

Applicants' arguments, filed 4/2/02, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

FIRST PARAGRAPH OF SPECIFICATION

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing

date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

CHANGE OF INVENTORSHIP:

In view of the papers, filed 4/2/02, it has been found that this application, as filed, through error and without any deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R. § 1.48. The inventorship of this application has been changed by addition of Yeasing Y. Yang.

DRAWING CORRECTION REQUIRED:

Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 8 on 7/10/96. Due to the above notification Applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

VAGUENESS AND INDEFINITENESS:

Claims 40, 50, 51, 54, 67-73, 75, 78-80, 82, 83, 96-99, 101, and 143-177 are rejected, as discussed below, under 35 U.S.C.

§ 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that the above listed claims either directly or via dependence cites the phrase "the sequence perfectly complementary thereto". Upon reconsideration of this phrase, the metes and bounds of it are unclear due to no clear limitation therein as to what is "perfect" for the complementary sequences. For example, if an oligonucleotide is totally and exactly complementary to a subsegment of a recited sequence but is shorter due to being complementary to only said subsequence, it is reasonable to interpret this complementarity to be a perfect complementarity over the length of said oligonucleotide. Alternatively, if an oligonucleotide is longer than a recited sequence but is exactly and totally complementary for that portion of said oligonucleotide which exactly complements the recited sequence then that complementarity is reasonably a perfect complement to the recited sequence. Yet another alternative is that the oligonucleotide is perfectly of the same length as the recited sequence but not completely complementary, or even complementary to some small percentage possibly. It is noted that the word "perfect" per se does not contain any recitation as to what characteristic(s) must be perfect in order to meet this limitation. Perfection of complementarity over

either an oligonucleotide or, alternatively, a recited sequence is also both a perfect type of complementarity as well as total complementarity, if present, when both the oligonucleotide and a recited sequence are of the same length and are exactly 100% complementary to each other. Thus, without a length limitation combined with a complementarity percentage or appropriate limitation to clarify what perfection is meant, any of the four situations outlined above may be a reasonable interpretation. Note that the lack of either of a length limitation or of a complementarity limitation opens up the number of length different or same oligonucleotide/recited sequence pairs to be infinite as to the number of length options that would be available albeit with requiring said complementarity to at least provide some type of perfect complement character. It is noted that applicants have alleged in their REMARKS, filed 4/2/02, that synonymous phrases are "fully complementary sequence of the same length thereof" and "sequence perfectly complementary thereto" but the above analysis supports this rejection in that they are not clearly interpretable as synonymous. Clarification via clearer claim wording is requested.

NOT FURTHER LIMITING CLAIMS

Claim 73 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 73 requires the primer of claim 71 being within or consisting of SEQ ID NOs: 1 or 19. The claim 71 and correspondingly claim 67 primer sequence has not been found within either of SEQ ID NOs: 1 or 19.

REJECTIONS BASED ON PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 96, 143, 158, 159, 166, 167, 175, and 177 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Shah et al. (P/N 5,521,300).

It is noted that instant SEQ ID NOs: 7 and 8 are identical to the exact complements of SEQ ID NOs. 84 and 48, respectively, of Shah et al. regarding subsegments thereof. The subsegment of

SEQ ID NO: 84 is bases 11-34 compared to instant SEQ ID NO: 7. The subsegment of SEQ ID NO: 48 is bases 19-41 compared to instant SEQ ID NO: 8. Thus, they are perfect complements within the unclear perfect complementary wording of the instant claims. See the above rejection under 35 U.S.C. § 112, second paragraph. Claim 5 of Shah et al. is directed to a probe mixture of various probes, one of which may be interpreted as a helper probe of instant claim 96 which is broadly defined instantly. Said claim 5 includes SEQ ID NO: 48 which thus anticipates instant claim 96. Instant claims 143 and 158 are directed to the perfect complement of instant SEQ ID NO: 7 which as noted above is anticipated by SEQ ID NO: 84 of Shah et al. It is also noted that instant claims 96, 158, 159, 166, 167, 175, and 177 are directed to hybridization regions which clearly are defined by SEQ ID NOs. 7 or 8 and thus additionally supports this rejection.

Claims 67, 68, 71, 75, 78, 84, 88, 147-149, 153, 158, 162, 166, and 173 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by either of Products O 0629 or O 8629 of the 1990 Sigma Chemical Company Catalog.

The products O 0629 (19-mer oligo dC) or O 8629 (18-mer oligo dT) have the characteristics that they serve as primers hybridizable to cited sequences from the instant claims and thus anticipate the above listed instant claims. The reference of Sommer et al. is cited herein only to document that primers for

PCR amplification are usable and characterized as such if they have 2-3 complementary bases to the target at their 3' end and are in the length range of 17-20 nucleotides. Two bases prime, however, weakly as noted in Sommer et al. It is firstly noted that the cited products are in this 17-20 nucleotide length range. It is noted that regarding instant claim 71, for example, that any RNA polymerase can initiate transcription and also can recognize any base as it synthesizes RNA from a template. The 3 base segments which supports the primer usability for the above noted products within each of the above rejected instant claims are listed as follows:

claim	product	target segment
67,68,71	O 0629	GGG - complement of SEQ ID NO: 22
75,78	O 8629	AA - SEQ ID NO: 23; AA or AAA - SEQ ID NO: 7 (first and sec. primers are same)
84,88	O 0629	GGG - SEQ ID NO: 22 (comp) and SEQ ID NO: 2 (first and sec. primers are same)
147-149,153	O 8629	AA - SEQ ID NO: 23
158	O 8629	AA - SEQ ID NO: 23; AA or AAA - SEQ ID NO: 7
158	O 0629	GGG - SEQ ID NO: 22 (comp)
162,173	O 0629	GGG - SEQ ID NO: 22 (comp)
166	O 8629	AA - SEQ ID NO: 23; AA or AAA - SEQ ID

NO: 7

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 39, 40, 67-71, 84, 86, 88, 150, 158, 162, and 173 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Boddington et al. [J. Clin. Microbiol. (1990) 28:1751] taken in view of Suzuki et al. [J. of Bact. (1988) 170(6):2886].

In the abstract and following introductory discussion on page 1751 of Boddington et al. the usability of specific sequence rRNA primers and probes is described. This motivates and suggests that such primers and/or probes may be generically utilized in either hybridization assays or PCR methods for

Mycobacterial detection given only description of sequence differences which would be usable to give specificity to such assays.

Suzuki et al. describes the entirety of the 16S rRNA sequence of *Mycobacterium bovis* BCG on page 2887 in Figure 2 along with sequence differences compared to other organisms therein listed as *E. coli* and *S. lividans*. Note the three sequences listings in the Figure. It is also noted that instant SEQ ID NOs: 2 and 3 are exactly present within said Figure 2 sequence regarding *M. bovis*. SEQ ID NO: 2 is at bases marked 141-171. SEQ ID NO: 3 is at bases marked 193-216. Lastly, the exact complement of instant SEQ ID NO: 22 is in Figure 2 at bases marked 244-265. These segments are arbitrary choices within the 16S rRNA of Suzuki et al. but have specificity characteristics as shown compared to the other microorganisms and thus are expected to be suitable probes and/or primers.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to chose sequence specific sections from Suzuki et al. to prepare specific hybridization probes and/or primers. Primers and/or probes made up of segments thereof as suggested and motivated in Boddinghaus et al. where sequence differences are shown as in Suzuki et al. would reasonably be expected to perform as specific primers and/or probes for selective *Mycobacteria* assays.

Claims 89, 90, 92, and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 41, 42, 48, 49, 55, 56, 95, 100, and 102-142 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 31, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.